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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,480	02/14/2006	Oskar Axelsson	PN0296	5067

36335 7590 05/16/2007

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EXAMINER	
FERNANDEZ, KATHERINE L	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/536,480	AXELSSON ET AL.	
	Examiner	Art Unit	
	Katherine L. Fernandez	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/24/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement filed on 5/24/2005 is acknowledged. The information disclosure statement meets the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein have been considered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-7, 12, 14-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larson et al. (Patent No. 6,278,893) in view of Werne (US Patent No. 5,782,764).

Regarding claims 1-3 and 5-7, 12, 14-15 and 17 Ardenkjaer-Larson et al. disclose a method of magnetic resonance investigation of a sample, preferably of a human or non-human animal body (Abstract). They disclose that their method involves administering a high T1 agent comprising nuclei selected from the group consisting of ^{3}H, ^{3}Li, ^{13}C, ^{15}N, ^{19}F and ^{31}P (column 27, line 64 through column 28, line 16). They further disclose that the high T1 agent a T1 value of at least 5 seconds at a field

strength of 0.001-5 T and a temperature of 20-40 degrees Celsius (column 28, lines 24-26).

However, they do not disclose that their method comprises also of an invasive device inserted into a human or non-human animal body and an MR image of at least a part of said body containing said device that is generated to visualize the device. Further, with regards to claim 5, they do not disclose that the invasive device contains a cavity for holding the contrast medium, the cavity preferably fitted with an outside duct for facilitating circulation and addition of contrast medium. With regards to claim 6, they do not disclose that the invasive device is made from a medium conductive material containing carbon fiber. Further, with regards to claim 7, they do not disclose that the invasive device is inserted into a tissue and/or vasculature of the human or non-human animal body. They also do not disclose, with regards to claim 12, that the method is a method for diagnosis by biopsy.

Werne discloses an invention that comprises of an invasive device wherein an operative or other portion of the instrument is marked with a contrast agent that is appropriate to the imaging modality, and the entire remaining portion of the instrument is made of carbon-fiber composite material (column 6, 55-65). Their method includes displaying an MR image of a selected cross-sectional portion of the target including the instrument (column 9, lines 21-26). With regards to claim 7, Werne discloses that a typical target is human tissue (Abstract, lines 12-18). Werne discloses an embodiment of the invasive device that consists of a thrusting biopsy needle made of a rigid material such as a carbon-fiber composite (column 11, lines 21-26). The device further includes

a contrast media-containing marker stylet (142) having a sharp distal end that is disposed within canula (140) (column 11, lines 26-28). The marker stylet contains a contrast agent that is encapsulated in a chamber formed by the inner cylindrical surface of the marker stylet and two bulkheads (144) oriented perpendicularly to the stylet (column 11, lines 28-32). See Figure 8. The device is advanced into a target (i.e. a patient from whom a biopsy sample is to be taken) while the assembly is imaged together with the sample (column 11, lines 35-42). At the time of the invention, it would have been obvious to one of ordinary skill in the art to include in the method of Ardenkjaer-Larson et al. an invasive device (that contains a cavity for holding the contrast medium and is made from a medium conductive material containing carbon fiber) inserted into a body and generate an MR image of at least a part of the body containing the device to visualize the device. The motivation for doing so would have been to apply the method for minimally invasive therapy, which is a cost-effective way to treat/diagnose a patient, as taught by Werne (column 3, lines 31-39).

Regarding claim 4, Ardenkjaer-Larson et al. disclose that the high T1 agent has a T1 value of at least 10 seconds or more, or 30 seconds or more, or 60 seconds or more, or more than 100 seconds at a field strength of 0.001-5 T and a temperature of 20-40 degrees Celsius (column 28, lines 30-38).

5. Claims 8-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larson et al. in view of Werne as applied to claims 1-7, 12, 14-15 and 17 above, and further in view of Kucharczyk et al. (US Patent No. 6,026,316).

Regarding claims 8-9, as discussed above, Ardenkjaer-Larson et al. in view of Werne meet the limitations of claim 1. However, they do not specifically disclose that the contrast medium additionally is a therapeutically active medium, nor that the therapeutic active medium is instilled at the region of interest via the invasive device. Kucharczyk et al. disclose a drug delivery device for targeted drug delivery into a patient using magnetic resonance (MR) imaging combined with conventional catheter placement techniques (column 1, lines 6-16). Their method involves the use of MRI with an MR observable delivery device, with MRI images viewed to determine the position of the delivery or medical device and changes in the environment where the delivery device is present as an indication of changes in the molecular environment (column 6, line 58 through column 7, line 7). They disclose an embodiment of their invention in which the delivery of drugs can also be tracked from magnetic field frequency shift caused by the drug or arising from agents (i.e. contrast agents) added with unique frequency shifts from those of the local protons (such as that created from F-19 or fluorine-19 agents found in or added to the drug) (column 8, lines 7-12). As can be seen from Figure 1, the drug/contrast agent can be instilled at the region of interest (in this case the brain) via the invasive device (4) (column 16, line 27 – column 17, line 3). At the time of the invention, it would have been obvious to have the contrast medium additionally be a therapeutically active medium, and have this therapeutically active medium be instilled at the region of interest via the invasive device. The motivation for doing so would have been that the availability of an MR-visible drug delivery device combined with MR-visible chemical or drug agents would make it

possible to obtain near real-time information on drug delivery during interventional procedures in an intra-operative MR system, as taught by Kucharczyk et al. (column 12, lines 8-24).

Regarding claim 11, Ardenkjaer-Larson et al. in view of Werne do not disclose that the method is a method for diagnosis and optional surgery on tumors. Kucharczyk et al. disclose that their MR-visible drug delivery device can deliver a diagnostic drug solution into the tissue (Abstract). Further, as can be seen from Figure 11, the method can be used to track the spatial distribution of a drug agent into the region of a brain tumor (column 10, lines 9-11; Figure 11). Further, they disclose that their invention can be used in medical and surgical applications, such as thoracic surgery and radiology, cardiac surgery and cardiology, neurosurgery, and oncology (column 12, lines 8-24). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the method of Ardenkjaer-Larson et al. be a method for diagnosis and optional surgery on tumors. The motivation for doing so would have been to obtain near real-time information during interventional procedures in an intra-operative MR system, as taught by Kucharczyk et al. (column 12, lines 8-24).

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larson et al. in view of Werne as applied to claims 1-7, 12, 14-15 and 17 above, and further in view of Quay et al. (US Patent No. 4,863,716).

As discussed above, Ardenkjaer-Larson et al. in view of Werne meet the limitations of claim 1. However, they do not specifically disclose that the method is a method of examining and optionally operating the fallopian tubes. Quay et al. disclose a

method for obtaining a superior image of the cervical cavity and fallopian tubes (column 1, lines 13-20). They further disclose that their method comprises imaging of the uterus and fallopian tubes by injecting a solution of a tubal patency NMRI contrast agent into the uterine cavity under sufficient pressure to cause the liquid to pass into the fallopian tubes (column 4, lines 39-48). The uterine and the fallopian tube surfaces are then imaged using NMRI procedures (column 4, lines 39-48). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have used the method of Ardenkjaer-Larson et al. in view of Werne to examine the fallopian tubes. The motivation for doing so would have been to be able to determine the presence of abnormalities causing infertility, as taught by Quay et al. (column 1, lines 13-20).

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larson et al. in view of Werne as applied to claims 1-7, 12, 14-15 and 17 above, and further in view of Goldenberg (US Patent No. 5,776,093).

As discussed above, Ardenkjaer-Larson et al. in view of Werne meet the limitations of claim 1. However, they do not disclose that the method is an ablation procedure where an additional compound effective in this ablation procedure is introduced through the invasive device. Goldenberg et al. disclose an method for imaging and treating hypoplastic, absent, anatomically displaced or ectopic tissues and organs and to a kit suitable for use therefor (column 1, lines 14-17). Their method comprises the steps of injecting the subject with an amount of magnetic resonance image enhancing agent to produce an enhanced MR image of the structure to be effected, where the imaging agent comprises an antibody/fragment which specifically

binds to said organ and tissue (column 2, lines 48-63). They further disclose an embodiment of their invention that provides an immunological method of ablating a cell by administering to the subject a composition comprising an antibody or fragment specific to a hormone receptor or growth factor receptor on a cell targeted for ablation, wherein the antibody or fragment is conjugated to a chemical or radiation ablation agent (column 3, line 65 through column 4, line 6). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the method be a method of an ablation procedure where an additional compound effective in this ablation procedure is introduced through the invasive device. The motivation for doing this would have been to have the method perform a therapeutic application for patients with lymphoma or certain immune diseases, as taught by Goldenberg et al. (column 5, lines 33-41).

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larson et al. in view of Werne as applied to claims 1-7, 12, 14-15 and 17 above, and further in view of Schenck et al. (US Patent No. 5,705,014).

As discussed above, Ardenkjaer-Larson et al. in view of Werne meet the limitations of claim 15. However, they do not disclose that the hollow elongated body is opaque to radio frequency radiation. Schenck et al. disclose MR compatible instruments (column 1, lines 6-10). They disclose that instruments made of a carbon fiber material optionally doped with a doping agent have minimal affect on radiofrequency fields, and do not affect the homogeneity of an applied homogenous magnetic field or an applied radiofrequency field (Abstract). At the time of the invention, it would have been obvious to one of ordinary skill in the arts to have the hollow

elongated body be opaque to radio frequency radiation. The motivation for doing so would have been that carbon fiber has been shown to be opaque to radio frequency radiation, as taught by Schenck et al. (Abstract).

9. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larson et al. in view of Kucharczyk et al..

Ardenkjaer-Larson et al. disclose that their method involves administering a high T1 agent comprising nuclei selected from the group consisting of ^{3}H, ^{3}Li, ^{13}C, ^{15}N, ^{19}F and ^{31}P (column 27, line 64 through column 28, line 16). They further disclose that the high T1 agent a T1 value of at least 5 seconds at a field strength of 0.001-5 T and a temperature of 20-40 degrees Celsius (column 28, lines 24-26). However, they do not disclose that this contrast medium is administered using an invasive device that comprises of a hollow elongated body with a first end and a second end, a first lumen extending from said first end to said second end and a second lumen extending from first end to said second end, characterized in that said first lumen is in communication with said second lumen near to second end. Kucharczyk et al. disclose an MR-compatible drug delivery device that comprises a variable-length concentric tubular assembly with porous and non-porous components (column 16, lines 27-33). A MR-visible multi-lumen (which could mean 2 or more lumens) catheter is formed by extruding a tubular assembly with both porous and non-porous components (column 16, lines 27-38). As can be seen from Figure 4, the multi-lumen catheter (4) has a first and second end (Figure 4). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have contrast agent of Ardenkjaer-Larson be administered

using a multi-lumen device with a first end and a second end. The motivation for doing so would have been to have multiple contrast agent release sources which would effectively disperse the agents over the region, as taught by Kucharczyk et al. (column 6, lines 48-55).

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larson et al. in view of Kucharczyk et al. as applied to claims 18-19 above and further in view of Schenck et al. (US Patent No. 5,705,014).

As discussed above, Ardenkjaer-Larson et al. in view of Kucharczyk meet the limitations of claim 18. Kucharczyk et al. disclose that an MR-visible catheter must be made of material that is biocompatible and MR-compatible, such as carbon fiber composites (column 4, lines 16-35). However, they do not disclose that the material is opaque to radio frequency radiation. Schenck et al. disclose MR compatible instruments (column 1, lines 6-10). They disclose that instruments made of a carbon fiber material optionally doped with a doping agent have minimal affect on radiofrequency fields, and do not affect the homogeneity of an applied homogenous magnetic field or an applied radiofrequency field (Abstract). At the time of the invention, it would have been obvious to one of ordinary skill in the arts to have the hollow elongated body be opaque to radio frequency radiation. The motivation for doing so would have been that carbon fiber has been shown to be opaque to radio frequency radiation, as taught by Schenck et al. (Abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SPE-3768